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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,428	12/15/2003	Alfred J. Moo-Young	CBR 3.0-017 CONT	3967

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EXAMINER	
CAPPS, KEVIN J	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/736,428	Applicant(s) MOO-YOUNG ET AL.	
	Examiner Kevin Capps	Art Unit 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Continuation Sheet from Advisory Action

1. The Rule 131 Declaration filed on April 9, 2007, has not been considered by the Examiner. Specifically, the Declaration has not been considered at this stage because Applicant has not provided good and sufficient reasons why the Declaration was not earlier presented. Further, even if the Declaration was considered at this stage and it was sufficient to overcome the rejections based on the Reed et al. reference, withdrawal of the rejection at this stage would require further search and consideration, which is not warranted after a final Office Action when Applicant has provided no reason why the Declaration was not earlier presented. Finally, other rejections are maintained against the claims, so they are not in condition for allowance even if the Reed et al. reference was withdrawn.

2. Applicant's request for reconsideration of the rejections has been considered, but is insufficient to overcome the rejections of record.

3. Regarding the Bardin et al. reference, Applicant again argues that the Bardin et al. reference is not enabled for transdermal delivery of MENT, and thus cannot be properly used in a § 103 rejection. Applicant points to the Declaration submitted by Dr. Bardin stating that at the time of filing his patent application, no work had been done on transdermal delivery of MENT. Applicant also accuses the Examiner of refusing to consider this Declaration. However, the Declaration was addressed by the current Examiner in paragraph 14 on p. 6 of the Office Action mailed on June 29, 2006, as well as in paragraph 19 on p. 7 of the Office Action mailed on December 5, 2006. The Examiner concluded the same thing as the previous Examiner; namely, that a non-

enabling reference may qualify as prior art for the purpose of determining obviousness under § 103, and that the Bardin et al. patent is sufficient motivation for the person of ordinary skill in the art to look for references which teach known formulations for transdermal delivery of 7α-methyl-19-nortestosterone, such as those disclosed by Reed et al. See also the discussion in paragraphs 6-9 of the Office Action mailed on October 25, 2005.

4. Applicant also argues that the concept of inherency should not be applied in obviousness rejections. However, it is well-settled law that inherent properties are present in known products as well as products rendered obvious by the prior art. See MPEP § 2145, paragraph II, which states, "Granting a patent on the discovery of an unknown but inherent function...'would re-move from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art'." Also see MPEP § 2112.01, paragraph I, which states, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established," (*In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)). Thus, the concept of inherent properties is appropriate for products that are anticipated by or are obvious from the prior art. Further, no limitations are in the claims that differentiate the instantly claimed formulations from those that would be arrived at by following the suggestions of the prior art. Therefore, the products arrived at by following the suggestions of the prior art must possess the herein-claimed properties.

5. Regarding the rejections under 35 USC § 103 using Jain et al. (US 5,780,050) as the primary reference, Applicant again argues that Jain et al. only disclose transdermal delivery of a genus of androgens, and they do not recognize the herein-claimed non-5α-reducible androgens as being preferred in transdermal systems. This line of argumentation was addressed in paragraph 48 of the Office Action mailed on December 5, 2006. Again, Jain et al. broadly teach transdermal delivery systems comprising a genus of androgens encompassing the herein-claimed non-5α-reducible androgens. Bardin et al. bridge the gap to the instantly claimed formulations by teaching that the non-5α-reducible androgen 7α-methyl-19-nortestosterone, which is encompassed by the genus of Jain et al., is preferred in transdermal delivery systems. Applicant again argues that the Bardin et al. patent should not be applied here because it is non-enabled. However, as discussed throughout the prosecution history, it provides sufficient motivation to select 7α-methyl-19-nortestosterone from within the genus disclosed by Jain et al. Further, there is reasonable expectation of success because Jain et al. teach that the entire genus of androgens, including 7α-methyl-19-nortestosterone, can be effectively employed in the transdermal formulations disclosed therein. Therefore, the § 103 rejection is properly maintained.